UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA
PHOENIX DIVISION

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION
This Document relates to:
Case No. 2:15-cv-1926-DGC

CASE No. 2:15-md-2641-DGC
MDL No.: 2641

~~**UNITED STATES DISTRICT COURT**~~
~~**SOUTHERN DISTRICT OF TEXAS**~~
~~**CORPUS CHRISTI DIVISION**~~

~~DENISE O'NEIL,~~

~~*Plaintiff,*~~
~~vs.~~

~~C.R. BARD, INC., a foreign corporation, and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation,~~

~~*Defendants.*~~

~~**COMPLAINT FOR DAMAGES**~~

~~**1. NEGLIGENCE**~~
~~**2. NEGLIGENT FAILURE TO WARN**~~
~~**3. STRICT LIABILITY FAILURE TO WARN**~~
~~**4. STRICT LIABILITY DESIGN DEFECT**~~
~~**5. STRICT LIABILITYMANUFACTURING DEFECT**~~
~~**6. BREACH OF EXPRESS WARRANTY**~~
~~**7. BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**~~
~~**9. FRAUDLEMENT CONCEALMENT**~~
~~**10. NEGLIGENT MISREPRESENTATION**~~
~~**11. FRAUDLEMENT MISREPRESENTATION**~~

~~**DEMAND FOR A JURY TRIAL**~~

PREFATORY COMMENT

This action was previously filed on July 24, 2015, the United States District Court, Southern District of Texas, Corpus Christi Division, but mistakenly omitted a Loss of Consortium claim on behalf of Plaintiff Gerald O'Neill. The Complaint also mistakenly

identified Denise O'Neill as Denise O'Neil. This Amended Complaint is filed to correctly allege a claim for Loss of Consortium and correctly identify Plaintiff as Denise O'Neill.

Plaintiff, DENISE O'NEILL, by and through her undersigned attorneys, hereby sues Defendants C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC. (collectively "Bard"), and allege as follows:

AMENDED COMPLAINT

PARTIES

Plaintiff

1. Plaintiff, DENISE O'NEILL, at all times relevant to this action is and was a citizen of the state of Texas and resides in Nueces County. On or about November 19, 2009, Plaintiff underwent placement of a Bard G2® Filter System ("G2 Filter") at the Christus Spohn Hospital in Alice, Texas. In or about May 2012, Plaintiff suffered cardiac complications because a fractured shard of the device about 1 inch long broke of the filter and migrated to and became embedded in her heart. Diagnostic imaging revealed not only that two struts had fractured and migrated, but also that the device was tilted and perforating her vena cava. Plaintiff required multiple medical procedures to remove the defective device and the fractured shard from her heart, and she continues to have another fractured piece lodged between her aorta and spine. Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, loss of enjoyment of life, and other losses. Plaintiff will require ongoing medical monitoring.

Defendants

2. Defendant C.R. Bard, Inc. ("Bard") is a foreign corporation authorized to do business in Florida and said Defendant was doing business in Broward County, Florida. Bard at

all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the G2® Filter System to be implanted in patients such as the Plaintiff throughout the United States, including Florida.

3. Defendant Bard Peripheral Vascular, Inc. ("BPV") is a wholly owned subsidiary corporation of Defendant C.R. Bard, and is a foreign corporation authorized to do business in Florida and said Defendant was doing business in Broward County, Florida. BPV, at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the G2® Filter System to be implanted in patients such as the Plaintiff throughout the United States, including Florida.

4. All references to "Bard" or "Defendants" hereafter shall refer to Defendants Bard and BPV.

JURISDICTION AND VENUE

5. Jurisdiction is proper in this Court under 28 U.S.C. § 1332(a) (1) because the Plaintiff and the Defendants are citizens of different states, and the amount in controversy exceeds seventy-five thousand dollars ($75,000.00), excluding interest and costs.

6. Venue is proper in this Court, as the facts and circumstances leading to injuries occurred in Jim Wells County, Texas and the Plaintiff currently resides in Nueces County, Texas. Further, the G2 Filter system that is the subject of this action was sold and purchased in Jim Wells County, Texas. Furthermore, the Defendant's herein were authorized to conduct business in the State of Florida and did conduct business in Jim Wells County, Texas.

GENERAL FACTUAL ALLEGATIONS

7. Plaintiff brings this case for serious personal injuries Plaintiff suffered as result of a surgically implanted medical device, known as a G2 Filter System (hereafter "G2 Filter"), fracturing, tilting, migrating within her body and perforating her vena cava causing serious and ongoing physical, emotional, and economic damages.

8. The G2 Filter was designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold by the Bard Defendants to prevent blood clots (thrombi) from travelling from the lower portions of the body to the heart and lungs.

9. Prior to Plaintiff being implanted with a G2 Filter, the Bard Defendants knew and should have known that the device was defective and unreasonably dangerous for, *inter alia*, the following reasons:

a. Bard did not have an appropriate and thorough understanding of vena caval dynamics when it designed, manufactured and tested the G2 Filter and when it sold and distributed the G2 Filter for implantation in humans such as the Plaintiff.

b. Bard failed to conduct appropriate animal studies, bench testing, and human clinical testing to determine how the device would function once permanently implanted in the human body.

c. Bard knew and/or should have known that the G2 Filter had an unreasonably high rate of fracture, migration, excessive tilting, perforating the vena cava wall once implanted in the human body. Bard knew and/or should have known that such failures exposed patients to serious injuries, including: death; hemorrhage; organ injury; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels and organs; otherwise unnecessary surgical procedures and

associated risks, and inability to remove the device. Further, Bard knew or should have known that these risks for the G2 Filter were and are substantially higher than other similar devices, including Bard's own Simon Nitinol Filter.

d. Bard also knew or should have known that the risk of fracture increased the longer a device was left implanted and/or if it tilted or perforated the vena cava. Yet, Bard chose to conceal this information from consumers and patients.

e. Bard knew that there was, and still is, no proven benefit to the use of IVC Filters, let alone the G2 Filter specifically, and yet there was clear evidence that the G2 Filter was causing serious injuries and death.

f. At the time the device implanted in Plaintiff, there were feasible alternative designs that would have substantially improved the safety of the G2 Filter in respect to tilting, perforation, fracture and migration and significantly reduced the risk of injury suffered by Plaintiff. These design changes include, but are not limited to, adding a chamfer, modifying the size and/or angle of the anchoring struts, modifying the number and location of anchoring struts, electropolishing the filter, and adding a "penetration limiter." Except for a chamfer, Bard did in fact later incorporate each of these safety changes into the design of the G2 Filter.

g. Bard was further aware or should have been aware that it was illegally marketing the G2 Filter and the Recovery Cone Removal System, which is used to retrieve the device, in violation of federal law. The FDA regulates medical device manufacturers by requiring that all manufacturers must obtain FDA clearance or approval prior to marketing a device for use in humans and by requiring that manufacturers voluntary adhere to minimum safety requirements in the design, manufacture, marketing and post-market surveillance of medical devices, which are laid out at 21 C.F.R. Sections 801, 803 and 820. Failure to comply with these requirements

renders a device adulterated and misbranded under federal law, and such devices may not be marketed. On July, 13, 2015, The FDA issued notice that it has found that both the G2 Filter and the Recovery Cone Removal System violate these requirements and that these devices are adulterated and misbranded under federal law.

h. Further, Bard knew and/or should have known that the G2 Filter was used to treat conditions of the type which the Plaintiff suffered from.

i. Despite being aware of these risks, its inadequate testing and their lack of a thorough understanding of vena caval dynamics, Bard misrepresented, omitted, and/or failed to provide adequate warnings of these risks or instructions for safe use.

j. Even when Bard designed and began marketing safer versions of the G2 Filter, including the Eclipse and Meridian Filters, it still failed to issue a recall, issue appropriate warnings and/or notify physicians and consumers that a safer device was available.

A. INFERIOR VENA CAVA FILTERS GENERALLY

10. Inferior vena cava ("IVC") filters first came onto the medical market in the 1960's. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

11. An IVC filter is a device that is designed to filter or "catch" blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either permanently or temporarily, in the human body, more specifically, within the inferior vena cava.

12. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, thrombi travel from the vessels in the

legs and pelvis, through the vena cava and into the lungs. Often times, these thrombi develop in the deep leg veins. These thrombi are called “deep vein thrombosis” or “DVT”. Once thrombi reach the lungs, they are considered “pulmonary emboli” or “PE”. Pulmonary emboli present significant risks to human health.

13. Certain people are at increased risk for the development of DVT or PE. For instance, an individual who undergoes knee or hip joint replacement surgery is at risk for developing DVT/PE. Obese patients are also at increased risk for DVT/PE. So too are people who have vascular diseases or who have experienced previous strokes. A number of other conditions predispose people to develop DVT/PE, including “coagulopathies” and clotting disorders.

14. Those people at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe anticoagulation medications such as Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE, or who are not candidates for anticoagulation medications may require the permanent or temporary implantation of an IVC filter to prevent thromboembolic events.

15. As indicated above, IVC filters have been on the market for decades. The first IVC filters marketed were permanent filters. These devices were designed to be implanted into the IVC permanently. These permanent filters have long-term follow-up data (of up to 20 years and longer) supporting their use and their safety. Beginning in 2003, manufacturers also began marketing what are known as optional or retrievable filters. These filters are designed so that they can be surgically removed from a patient after the risk of PE has subsided. Some of these IVC filter designs were not intended to remain within the human body for indeterminate periods of time but were intended to remain implanted for a finite period of time. The Recovery® Filter

and the subsequent G2® Filter manufactured by Bard, however, are examples of filters that were ultimately marketed as both permanent and retrievable filters.

B. THE RECOVERY FILTER®

i. FDA Clearance and Intended Use

16. In 2002, Bard and BPV submitted a notification to market the "Recovery Filter System" (hereafter "Recovery Filter") for the prevention of recurrent pulmonary embolism by placement in the inferior vena cava.[1] On November 27, 2002, the FDA cleared the device for sale and use in the prevention of recurrent pulmonary embolism via *permanent* placement in the vena cava.

17. In April 2003, Bard submitted a notification of intent to market and sell the RECOVERY® Filter for the additional intended use of *optional retrieval* and Bard received FDA clearance to begin marketing the Recovery Filter as both a permanent and retrievable filter on or about July 25, 2003.

18. Soon after receiving the indication for optional retrieval Bard began selling a device known as the Recovery Cone Removal System. Bard labeling warned that the only safe way to remove the Recovery Filter was using its Recovery Cone Removal System. However, Bard never sought not obtained clearance via the premarket notification process (510k) or approval through the more stringent pre-market approval process to market this device. Thus,

[1] Bard and BPV submitted the notification under Section 510(k) of the United States Food, Drug and Cosmetic Act ("Act") of 1976 (21 U.S.C. 321 *et seq*). The 510(k) review process requires any entity engaged in the design, manufacture, distribution or marketing of a device intended for human use to notify the FDA 90 days before it intends to market the device and to establish that the device is substantially equivalent to a legally marketed predicate device. (21 C.F.R. §§ 807.81, 807.92(a)(3)). Substantial equivalence means that the new device has the same intended use and technological characteristics as the predicate device. This approval process allows a manufacturer to bypass the rigorous safety scrutiny required by the pre-market approval process.

Bard was illegally marketing this device and there has never been a device cleared by the FDA as safe and effective for retrieving the Recovery Filter. This was first disclosed to the public on July 13, 2015.

19. Bard was aware and actively promoted the Recovery filter off-label uses, including purely prophylactic reasons for trauma patients or patients with upcoming surgeries such as bariatric procedures.

ii. Design of the Recovery Filter

20. The Recovery Filter is conical in shape and it consists of two (2) levels of six (6) radially distributed NITINOL struts that are designed to anchor the filter into the inferior vena cava and to catch any embolizing clots. There are six short struts, which are commonly referred to as the arms, and six long struts, which are commonly referred to as the legs. Each strut is held together by a single connection to a cap located at the top/apex of the device. According to the Patent filed for this device, the short struts are primarily for "centering" or "positioning" within the vena cava, and the long struts with attached hooks are designed to primarily prevent the device from migrating in response to "normal respiratory movement" or "pulmonary embolism."

21. As noted above, the Recovery Filter is constructed with NITINOL, which is an acronym that stands for Nickel Titanium Naval Ordnance Laboratory. NITINOL possesses "shape memory." That is, NITINOL will change shape according to changes in temperature, and then, retake its prior shape after returning to its initial temperature. When placed in saline, therefore, the NITINOL struts become soft and can be straightened to allow delivery through a small diameter catheter. The metal struts then reassume their original shape when warmed to body temperature in the vena cava.

22. The Recovery filter is inserted percutaneously by a catheter that is guided by a physician through a blood vessel into the inferior vena cava. The Recovery Filter is designed to be retrieved in a similar fashion.

iii. Risks of the Recovery Filter.

23. The Recovery Filter is prone to an unreasonably high risk of failure and patient injury following placement in the human body. Multiple studies have reported Bard's Recovery Filter to have a fracture and migration rate ranging from 21% to 31.7%. When such failures occur, shards of the device or the entire device can travel to the heart, where it can cause cardiac tamponade, perforation of the atrial wall, perforation of vessels, myocardial infarction and death. These fractured shards may also become too embedded in tissue or migrate to other organ systems and vasculature, such as the renal veins, heart and lungs, rendering them too dangerous to remove. These patients are exposed to a lifetime of future risk.

24. The Recovery Filter similarly poses a high risk of tilting and penetrating and perforating the vena cava walls. When such failures occur, the device can perforate nearby organs and vessels such as the aorta, duodenum, small bowel, ureter, which may lead to hemorrhage, retroperitoneal hematomas, small-bowel obstructions, extended periods of severe pain, and/or death. Further, given the risks of injury in attempting to remove devices that have penetrated or perforated the vena cava, the device may not be removable or may require complex and dangerous open vascular surgical removal. These patients in whom the filter cannot be removed are faced with a lifetime of future risk.

25. The Recovery Filter failures described above occur at a substantially higher rate than with other IVC filters including Bard's own Simon Nitinol Filter.

26. The adverse event reports (AERs) associated with IVC filter devices demonstrates that Bard's IVC Filters to include the Recovery Filter are far more prone to device failure than are other similar devices including Bard's own Simon Nitinol Filter.

27. These failures are attributable, in part, to the fact that the Recovery Filter was designed so as to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

28. In addition to design defects, the Recovery Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the absence of electropolishing and the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the device while *in vivo*. In particular, the Recovery Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the Recovery Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to failure.

iv. What Bard Knew or Should Have Known

29. Bard was well aware that it lacked a thorough and/or appropriate understanding of vena caval dynamics. Bard did not conduct a clinical study of long term safety and efficacy, nor did it perform adequate animal studies and bench testing to determine whether the Recovery Filter would perform safely once implanted in the human body and subjected to normal *in vivo* stresses.

30. Soon after the Recovery Filter's introduction to the market in 2003, Bard began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the Recovery Filter was fracturing or migrating post-implantation and that fractured pieces and/or the entire device were migrating throughout the human body, including to other vessels, the heart and lungs. Bard also received large numbers of AERs reporting that the Recovery Filter was found to have excessively tilted, migrated and/or perforated the inferior vena cava post-implantation and that the filter cannot removed or removal can only be achieved through complex and dangerous open vascular surgery. These failures were often associated with reports of severe patient injuries such as:

i. death;

ii. hemorrhage;

iii. cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

iv. cardiac arrhythmia and other symptoms similar to myocardial infarction;

v. severe and persistent pain;

vi. and perforations of tissue, vessels and organs.

31. Bard received AERs reporting that the Recovery Filter had fractured *in vivo* and that the entire device had migrated, some of which were reported to have been associated with patient death.

32. From 2003 through September 2005, Bard received increasing numbers of AERs reporting the above described failures and patient injuries.

33. Bard knew that the failure rates associated with the Recovery Filter including death were substantially higher than other similar devices on the market including its own Simon

Nitinol Filter and that the adverse event rates associated with the Recovery Filer compared with other filters was statistically significant.

v. Bard Conducts Silent Recall of Recovery Filter

34. In 2004 Bard, without notifying consumers of the design and manufacturing flaws inherent in the Recovery Filter and to avoid a recall of the Recovery Filter, began redesigning the Recovery Filter in an attempt to correct those flaws. The redesigned filter is known as the G2 Filter, which stands for second generation Recovery Filter. Once Bard began marketing and selling the redesigned product in approximately August 2005, Bard quietly stopped selling the Recovery Filter. However, Bard failed to make any effort to notify physicians and consumers who were implanted with the Recovery Filter of the ongoing risks inherent in the use of the Recovery Filter.

C. THE G2 FILTER SYSTEM

35. On August 29, 2005, Bard obtained clearance to market the G2 Filter through the 510k process by having represented to the FDA that the G2 Filter was substantially equivalent in respect to safety and efficacy as the Recovery Filter. Bard represented that the differences between the Recovery Filter and the G2 Filter were primarily dimensional and no material changes or additional components were added. The G2 Filter was only cleared for permanent implantation until January 15, 2008. Thus, between September 2005 through all of 2007, Bard sold two filters, the Simon Nitinol Filter and G2 Filter, with the exact same indications for use.

36. As with the Recovery Filter, Bard sold a medical device known as the Recovery Cone Removal System to be used to retrieve the G2 Filter. Bard's labeling again warned that the only safe way to retrieve the G2 Filter was by using the Recovery Cone Removal System. However, Bard again failed to seek or obtain clearance or approval from the FDA to market the

Recovery Cone Removal System. Thus, Bard was illegally marketing this device and there has never been a device cleared by the FDA as safe and effective for retrieving the G2 Filter. This was first disclosed to the public on July 13, 2015.

37. Bard marketed the G2 Filter as having "enhanced fracture resistance," "improved centering," and "increased migration resistance" over all of its previous filters. However, Bard knew these claims were false and misleading. Bard knew that the Simon Nitiniol Filter was less likely to fracture, migrate, tilt, or perforate the vena cava. Further, Bard again failed to conduct adequate clinical testing for long term safety and efficacy and filed to conduct adequate bench testing and animal studies, to ensure that the device would perform safely and effectively once implanted in the human body and subjected *in vivo* stresses. Furthermore, Bard still did not have a thorough and/or adequate understanding of vena caval dynamics. Not surprisingly, the G2 Filter's design causes it to be of insufficient integrity and strength to withstand normal *in vivo* body stresses within the human body so as to resist fracturing, migrating, tilting, and/or perforating the inferior vena cava.

38. Also, like its predecessor, in addition to design defects, the G2 Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the absence of electropolishing and the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2 Filter while *in vivo*. In particular, the G2 Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the G2 Filter is not of sufficient strength to withstand normal placement within the human body. The presence

of the aforementioned exterior manufacturing defects makes the device more susceptible to fatigue failure and migration.

39. Thus, the G2 Filter shares similar defects and health risks as its predicate/predecessor device.

40. As with the Recovery Filter, Bard immediately began receiving large numbers of AERs reporting that the G2 Filter was, *inter alia*, fracturing, migrating, excessively tilting, and perforating the vena cava once implanted. These failures were again often associated with reports of severe patient injuries such as:

a. death;

b. hemorrhage;

c. cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. severe and persistent pain;

f. and perforations of tissue, vessels and organs.

41. Bard represents the fracture rate of the G2 Filter to be 1.2%. Based upon a review of the data available in the public domain (including the FDA MAUDE database statistics and the published medical literature), this representation does not accurately reflect the true incidence of device fracture for the G2 Filter.

42. A review of the MAUDE database reveals data to establish that the Bard vena cava filters (including the G2® Filter) are responsible for the majority of all reported adverse events related to inferior vena cava filters.

43. Bard was aware as early as October 2005 that the G2 Filter System was defective and unreasonably dangerous and was causing injury and death to patients who had received it.

44. Data establishes that the failure rates of the Recovery® Filter and G2® Filter are/were exceedingly higher than the rate that Bard has in the past, and currently continues to publish to the medical community and members of the public. Further, Bard was aware or should have been aware that the G2 Filter had substantially higher failure rates than did other similar products on the market, including the Simon Nitinol Filter, yet Bard failed to warn physicians and consumers of this fact.

45. At the time, Plaintiff's filter was distributed, Bard was aware of numerous ways that the G2 could have been made safer. These include, but are not limited to, adding a chamfer, improving the anchoring mechanism, electropolishing filter, and adding penetration limiters. As Bard began introducing these design changes in modified devices starting with the Eclipse in January 2010, Bard again conducted a silent recall simply stopped selling the unsafe G2 Filter. However, no recall was ever issued.

46. From the time the G2 Filter System became available on the market, Bard embarked on an aggressive campaign of "off label marketing" concerning the G2 Filter System. This included representations made to physicians, healthcare professionals, and other members of the medical community that the G2 Filter System was safe and effective for retrievable use.

47. The conduct of Bard as alleged in this Complaint constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of the Plaintiff. Bard had actual knowledge of the dangers presented by the Recovery Filter and G2 Filter, yet consciously failed to act reasonably to:

a. Inform or warn Plaintiff, Plaintiff's physicians, or the public at large of these dangers;

b. Establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the Recovery Filter and G2 Filter from the market.

48. Despite having knowledge of the unreasonably dangerous and defective nature of the G2 Filter, Bard consciously disregarded the known risks and continued to actively market and offer for sale the G2 Filter System.

49. Plaintiff further alleges that Bard acted in willful, wanton, gross and total disregard for the health and safety of the users or consumers of their Recovery Filter and G2 Filter Systems, acted to serve their own financial interests, and having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

D. THE RECOVERY CONE REMOVAL SYSTEM

50. Bard marketed a medical device known as the Recover Cone Removal System to be used with the Recovery Filter and G2 Filter. Specifically, Bard's labeling instructed doctors that the Recovery Cone Removal System was the only method to safely remove the Recovery Filter and G2 Filter.

51. However, Bard never sought nor obtained clearance via the premarket notification process (510k) or approval through the more stringent pre-market approval process to market this device. Thus, Bard was illegally marketing this device and there has never been a device

cleared by the FDA as safe and effective for retrieving the Recovery Filter or G2 Filter. This was first disclosed to the public on July 13, 2015.

52. There have been numerous reports of the Recovery Cone Removal System failing, such as causing the filters themselves to break and/or not being able retrieve the filters.

53. As these devices were never cleared for marketing, Bard has in essence subjected all patient who have undergone removal of a Recovery or G2 Filter, which includes Plaintiff, to an illegal research trial without the safeguards and oversight of an approved clinical trial and/or without their informed consent.

E. FDA WARNING LETTER

54. On July 13, 2015, the FDA issued a warning letter notifying Bard that its IVC Filters and Recovery Cone Removal Systems are adulterated and misbranded under federal law.

55. The FDA noted that the Recovery Cone Removal Systems are adulterated pursuant to 501(f)(1)(B) of 21 U.S.C. § 351(f)(1)(B) and misbranded pursuant to section 21 U.S.C. 352(o) because these devices have never been cleared or approved for use in humans. Thus, the FDA demanded that Bard immediately cease commercial distribution of its Recovery Cone Removal Systems.

56. The FDA also notified Bard that its IVC Filters are adulterated and misbranded because the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Section 820, and that Bard failed to comply with adverse event reporting requirements of 21 C.F.R. 803.

57. The FDA cites numerous specific violations, including the failure to establish and maintain procedures to ensure that product complaints are adequately investigated and reported, and a consistent pattern of Bard underreporting the severity of injuries caused by device failures and failing to report device malfunctions all together. For instance, the FDA cites numerous examples of Bard reporting G2 Filter device failure resulting in death and other serious injuries as if there was no patient injury involved. Other examples of Bard's failures, include the FDA finding Bard failed to establish and maintain a procedure to ensure that the toxic acids and chemicals used in the manufacture of its filters were reduced to acceptable levels prior to distribution.

58. Aside from demanding that Bard cease all sales and marketing of the Recovery Cone Removal Systems, the FDA further demanded that with 15 Bard must explain "the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again."

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

59. On November 17, 2009 Plaintiff underwent surgical placement of a G2® Filter.

60. This G2® Filter device was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Bard.

61. In or about May 2012, Plaintiff suffered cardiac complications because a fractured shard of the device about 1 inch long broke off the filter and migrated to and became embedded in her heart.

62. Diagnostic imaging revealed not only that two struts had fractured and migrated, but also that the device was tilted, migrated, and was perforating her vena cava. Plaintiff required

multiple medical procedures to remove the defective device and the fractured shard from her heart, and she continues to have another fractured piece lodged between her aorta and spine.

63. Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, loss of enjoyment of life, and other losses. Plaintiff will require ongoing medical monitoring.

64. Upon information and belief, Plaintiff alleges that a Bard Recovery Cone System was used in the removal of her device.

FRUADULENT CONCEALMENT

65. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by Bard when they had a duty to disclose those facts. They have kept Plaintiff and her physicians ignorant of vital information essential to the pursuit of their claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing on her causes of action. Bard's fraudulent concealment did result in such delay.

66. Bard is estopped from relying on the statute of limitations defense because Bard failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the Recovery® and G2® Filter Systems.

67. Plaintiff and Plaintiff's health care providers could not reasonably have discovered the claims made herein until at the earliest the device was discovered to have tilted, migrated and perforated the Plaintiff's IVC and when she learned of her health care provider's inability to percutaneously remove the filter.

68. Bard was under a continuing duty to disclose the true character, quality and nature of the device that was implanted in the Plaintiff, but instead they concealed them. Bard's

conduct, as described in this Complaint, amounts to conduct purposely committed, which Bard must have realized was dangerous, needlessly reckless, without regard to the consequences or the rights and safety of Plaintiff.

TOLLING

69. Plaintiff and Bard entered into an agreement on March 31, 2012, whereby all statutes of limitations, statutes of repose, or any other laws, statutes or codes of any jurisdiction that define, limit, prescribe and/or restrict the time period within which Plaintiff's claims could be brought were tolled.

CORPORATE/VICARIOUS LIABILITY

70. At all times herein mentioned, the Bard Defendants were the agents, servants, partners, co-conspirators and/or joint venturers of each of the other and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

71. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between the Bard Defendants such that any individuality and separateness between these Bard Defendants has ceased and these Defendants are the alter ego of the other and exerted control over one another. Adherence to the fiction of the separate existence of the Bard Defendants as entities distinct from each other will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

72. At all times herein mentioned, the Bard Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of

researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiff. As such, each Bard Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

73. At all times herein mentioned, the officers and/or directors of the Bard Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of the Recovery Filter and G2 Filter, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

COUNT I - NEGLIGENCE

74. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-73 as though fully set forth herein.

75. At all times relevant to this cause of action, the Bard Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the G2 Filters.

76. Bard designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the G2 Filter that was implanted in Plaintiff.

77. Bard had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the G2 Filter so as to avoid exposing others to foreseeable and unreasonable risks of harm.

78. Bard knew or reasonably should have known that the G2 Filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

79. At the time of manufacture and sale of the G2 Filter, Bard knew or should have known that the G2 Filter:

a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. Was designed and manufactured so as to present a unreasonable risk of migration of the device and/or portions of the device; and/or

c. Was designed and manufactured so as to present a unreasonable risk of the device tilting and/or perforating the vena cava wall and/or could not be removed percutaneously;

d. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

80. At the time of manufacture and sale of the G2 Filter, Bard knew or should have known that using the G2 Filter as intended or in a reasonably foreseeable manner created a significant risk of a patient suffering and severe health side effects including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the

device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

81. Bard knew or reasonably should have known that consumers of the G2 Filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

82. Bard breached their to duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the G2 Filter in, among other ways, the following acts and omissions:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other device available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. Failing to use reasonable care to warn or instruct, including pre and post-sale, Plaintiff, Plaintiff's physicians, or the general health care community about the Recovery Filter and G2 Filter's substantially dangerous condition or about facts making the product likely to be dangerous;

e. Failing to perform reasonable pre and post-market testing of the Recovery Filter and G2 Filter to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Recovery Filter and G2 Filter;

g. Advertising, marketing and recommending the use of the Recovery Filter and G2 Filter, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of these filter systems;

h. Representing that the Recovery Filter and G2 Filter were safe for their intended use when, in fact, Bard knew and should have known the products were not safe for its intended purpose;

i. Continuing to manufacture and sell the Recovery Filter and the G2 Filter with the knowledge that said products were dangerous and not reasonably safe, and failing to comply with good manufacturing regulations;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Recovery Filter and the G2 Filter so as to avoid the risk of serious harm associated with the use of these filter systems;

k. Advertising, marketing, promoting and selling Recovery Filter and G2 Filter for uses other than as approved and indicated in the product's label;

l. Failing to establish an adequate quality assurance program used in the manufacturing of the Recovery Filter and G2 Filter.

m. Failing to establish and maintain and adequate post-market surveillance program;

n. By marketing the device as retrievable when it knew there was no device cleared as safe and effective to retrieve the device by the FDA.

o. Failing to remove the G2 Filter from the market; and,

A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

83. As a direct and proximate result of the foregoing negligent acts and omissions by the Bard Defendants, Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, mental anguish, loss of enjoyment of life, and other losses proximately caused by the device. Plaintiff is also exposed risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the fractured G2 Filter strut to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

COUNT II - NEGLIGENT FAILURE TO WARN

84. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 84 as though fully set forth herein.

85. Bard designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the G2® Filter, including the one implanted into Plaintiff, and the Recovery Cone Removal System into the stream of commerce

and in the course of same, directly advertised and marketed the devices to consumers or persons responsible for consumers.

86. At the time Bard designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the devices into the stream of commerce, Bard knew or should have known the devices presented an unreasonable danger to users of the products when put to their intended and reasonably anticipated use. Specifically, Bard knew or should have known at the time they manufactured, labeled, distributed and sold the G2 Filter, which was implanted in Plaintiff, that the G2 Filter, *inter alia*, posed a significant and higher risk for fracture, migration, tilting, perforation of the vena cava wall and an inability to remove the filter percutaneously and resulting serious injuries, including death, than other similar devices, including Bard's own Simon Nitinol Filter.

87. Bard was also aware prior to the G2 Filter implanted in Plaintiff being distributed, that Recovery Cone Removal System could not be legally marketed in the United States. Thus, Bard knew there was no FDA cleared or approved method for safely retrieving the G2 Filter.

88. Therefore, Bard had a duty to warn about the particular risks of the G2 Filter and to provide adequate instructions on the safe and proper use of the device. Bard further had a duty to warn of dangers and proper safety instructions that it became aware of even after the device was distributed and implanted in the Plaintiff. The Defendant's knew or should have known that the G2 Filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

89. Bard also had a duty to warn of that its retrieval device could not be legally marketed or used in the United States and thus there was no FDA cleared or approved method for removing these devices.

90. Despite this duty, Bard failed to adequately warn of material facts regarding the safety and efficacy of the G2® Filter, and further failed to adequately provide instructions on the safe and proper use of the device.

91. No health care provider or patient, including Plaintiff and her physicians, would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.

92. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

93. Plaintiff and Plaintiff's health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

94. Therefore, the G2 Filter implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

95. The G2 Filter implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Bard.

96. As a direct and proximate result of the foregoing negligent acts and omissions by the Bard Defendants, Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, mental anguish, loss of enjoyment of life, and other losses proximately caused by the device. Plaintiff is also exposed risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the fractured G2® Filter strut to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

COUNT III - STRICT LIABILITY FAILURE TO WARN

97. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-96 as though fully set forth herein.

98. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the G2 Filter, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

99. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically, Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the G2® Filter, which was implanted in Plaintiff, that the G2 Filter, *inter alia*, posed a significant and higher risk than other similar devices of device failure (fracture, migration, tilting, and perforation of the vena cava wall) and resulting serious injuries. Bard also knew that there were specific design problems with the G2 Filter, that were resulting in product failures, such as Bard's failures to include a chamfer, electropolish the filter, have the appropriate anchoring technology, and yet Bard failed to warn the public of these problems. Bard also falsely marketed the product as being less likely to tilt, fracture, and migrate than it permanent filter, the Simon Nitinol Filter. Finally, Bard also downplayed the risk of harm by just stating that serious injuries had been reported but failing to warn that serious injuries, including, death had been confirmed to have resulted from failures of the G2 Filter.

100. Therefore, Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device. Defendants further had a duty to warn of dangers and proper safety instructions that it became aware of even after the device was distributed and implanted in Plaintiff.

101. Despite this duty, Defendants failed to adequately warn of material facts regarding the safety and efficacy of RECOVERY® Filter, the G2® Filter and further failed to adequately provide instructions on the safe and proper use of the device. Furthermore, the foreseeable risks of harm from the G2 Filter could have been reduced or avoided by providing reasonable instructions and/or warnings and the failure to provide those instructions or warnings makes the G2 Filter unreasonably dangerous and renders the device defective.

102. Bard was also aware prior to the G2 Filter implanted in Plaintiff being distributed, that Recovery Cone Removal System could not be legally marketed in the United States. Thus, Bard knew there was no FDA cleared or approved method for safely retrieving the G2 Filter. Thus, Bard also had a duty to warn of that its retrieval device could not be legally marketed or used in the United States and thus there was no FDA cleared or approved method for removing these devices.

103. No health care provider, including Plaintiff's, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.

104. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

105. Plaintiff and Plaintiff's health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

106. Therefore, the G2 Filter implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

107. The G2 Filter implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

108. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, mental anguish, loss of enjoyment of life, and other losses proximately caused by the device. Plaintiff is also exposed risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the fractured G2 Filter strut to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

COUNT IV - STRICT PRODUCTS LIABILITY DESIGN DEFECT

109. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-108 as though fully set forth herein.

110. At all times relevant to this action, Bard developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the G2 Filter, including the one implanted in Plaintiff.

111. The G2 Filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Bard's possession. In the alternative, any changes that were made to the G2 Filter implanted in Plaintiff were reasonably foreseeable to Bard.

112. The G2® Filter implanted in the Plaintiff was in a condition unreasonably dangerous and was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left the Defendant's possession. In the alternative, any changes that were made to the filter were reasonably foreseeable to the Defendant's.

113. The G2 Filter implanted in the Plaintiff was defective in design because it failed to perform as safely as an ordinary consumer would expect when used as intended, or when used in a manner reasonably foreseeable by the Defendant's and/or the risk of danger in the design outweighed the benefits of the filter.

114. Feasible design changes existed at the time it the G2 filter implanted in Plaintiff was distributed, that would have rendered substantially less likely to fail and caused the injuries it did in this case.

115. Plaintiff and Plaintiff's health care providers used the G2 Filter in a manner that was reasonably foreseeable to Bard.

116. Neither Plaintiff, nor Plaintiff's health care providers could have by the exercise of reasonable care discovered the devices defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the device.

117. As a direct and proximate result of the G2 Filter's defective design, Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, mental anguish, loss of enjoyment of life, and other losses proximately caused by the device. Plaintiff is

also exposed risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the fractured G2 Filter strut to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

COUNT V - STRICT LIABILITY MANUFACTURING DEFECT

118. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-117 as though fully set forth herein.

119. Bard designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the G2 Filter that was implanted into Plaintiff. The G2 Filter was unreasonably dangerous because of a manufacturing defect in that it was different from its intended design and failed to perform as safely as the intended design would have performed.

120. The G2 Filter implanted in Plaintiff was in a condition unreasonably dangerous and the filter was expected to and did reach the Plaintiff and/or her physicians without substantial change affecting the filter.

121. Plaintiff and Plaintiff's health care providers used the device in a manner that was reasonably foreseeable to Bard.

122. As a result of this condition, the product injured Plaintiff and failed to perform as safely as an ordinary consumer would expect when used in a reasonably foreseeable manner.

123. As a direct and proximate result of the G2 Filter's manufacturing defect, Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, mental anguish, loss of enjoyment of life, and other losses proximately caused by the device. Plaintiff is also exposed risk of requiring additional medical and surgical procedures, including risk of life

threatening complications and ongoing medical care to monitor the fractured G2 Filter strut to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

COUNT VI - BREACH OF EXPRESS WARRANTY OF MERCHANTABILITY

124. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-123 as though fully set forth herein.

125. At all times relevant to this action, Bard designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the G2 Filter for use as a surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

126. At the time and place of the sale, distribution, and supply of the G2 Filter System to Plaintiff by way of Plaintiff's health care providers and medical facilities, Bard, through sales representatives, consultants, printed materials and other advertising and marketing efforts expressly represented and warranted that the G2 Filter System was safe and effective for its intended and reasonably foreseeable use and that the device could be retrieved using a Bard Recovery Cone Removal System.

127. The G2 Filter System did not conform to the express representations made by Defendants through sales representatives, consultants, printed materials, and other advertising and marketing efforts. The Plaintiff and her physicians relied on these express representations in the purchase, use and implantation of the G2 Filter in the Plaintiff.

128. Bard knew of the intended and reasonably foreseeable use of the G2 Filter, at the time they marketed, sold, and distributed the product for use by Plaintiff, and warranted the product to be of merchantable quality, and safe and fit for its intended use.

129. Bard represented and warranted to the healthcare community, Plaintiff and Plaintiff's health care providers, that the G2 Filter was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

130. The representations and warranties made by Bard were false, misleading, and inaccurate because the G2 Filter was defective and unreasonably dangerous, there was no FDA cleared device to remove it, and the device was not of merchantable quality when used in its intended and/or reasonably foreseeable manner. At the time of Plaintiff's purchase of the G2 Filter from Bard regarding centering of the filter, fracture, migration, excessive tilting, and perforation of the inferior vena cava:

a. It was designed in such a manner so as to result in a statistically significant incidence of injury to the organs and anatomy; and

b. It was manufactured in such a manner so that the exterior surface of the G2 Filter System was inadequately, improperly and inappropriately prepared and/or finished causing the device to weaken and fail.

131. Plaintiff and Plaintiff's health care providers reasonably relied on the superior skill and judgment of Bard as the designers, researchers and manufacturers of the product, as to whether G2 Filter was of merchantable quality and safe and fit for its intended use, and also relied on the warranty of merchantability and fitness for the particular use and purpose for which the G2 Filter was manufactured and sold.

132. Bard placed the G2 Filter into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the G2 Filter was manufactured and sold.

133. Bard breached their warranty because their G2 Filter was not fit for its intended use and purpose.

134. As a proximate result of the Bard Defendants breach of their implied warranties, Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, mental anguish, loss of enjoyment of life, and other losses proximately caused by the device. Plaintiff is also exposed risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the fractured G2® Filter strut to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

COUNT VII - BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

135. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-134 as though fully set forth herein.

136. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the G2 Filter for use as a retrievable surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

137. At the time and place of the sale, distribution, and supply of the Defendants' G2 Filter to Plaintiff by way of Plaintiff's health care providers and medical facilities, Defendants expressly represented and warranted, by labeling materials submitted with the product, that the G2 Filter System was safe and effective for its intended and reasonably foreseeable use, and that it could be retrieved at any time by use of the Recovery Cone Removal System.

138. Defendants knew of the intended and reasonably foreseeable use of the G2 Filter and the Recovery Cone Removal System, at the time they marketed, sold, and distributed the products for use by Plaintiff, and impliedly warranted the products to be of merchantable quality, and safe and fit for its intended use. Defendants impliedly represented and warranted to the healthcare community, Plaintiff and Plaintiff's health care providers, that the G2 Filter and Recovery Cone Removal System were of merchantable quality and fit for their ordinary purposes for which the products were intended and marketed.

139. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the G2 Filter and the Recovery Cone Removal System were defective and unreasonably dangerous, and not of merchantable quality when used in their intended and/or reasonably foreseeable manner. Specifically, at the time of Plaintiff's purchase of the products from the Defendants, through Plaintiff's physicians and medical facilities, it was not in a merchantable condition in that:

a. It was designed in such a manner so as to be prone to a statistically high incidence of failure, including fracture, migration, excessive tilting, and perforation of the inferior vena cava;

b. It was designed in such a manner so as to result in a statistically significant incidence of injury to the organs and anatomy; and

c. It was manufactured in such a manner so that the exterior surface of the G2 Filter System was inadequately, improperly and inappropriately prepared and/or finished causing the device to weaken and fail.

d. There was no FDA device cleared or approved as safe and effective to be able to retrieve the device despite Bard's labeling stating that the Recovery Cone Removal System could be used for this purpose.

140. Plaintiff and Plaintiff's health care providers reasonably relied on the superior skill and judgment of Defendants as the designers, researchers and manufacturers of the product, as to whether G2 Filter was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the G2 Filters were manufactured and sold.

141. Defendants placed the G2 Filters into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the G2 Filter was manufactured and sold.

142. Defendants breached their implied warranty because the G2 Filters and Recovery Cone Removal Systems are not fit for their intended use(s) and/or the use(s) reasonably foreseeably by the Defendant.

143. As a proximate result of Defendants breach of their implied warranties, Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, mental anguish, loss of enjoyment of life, and other losses proximately caused by the device. Plaintiff is also exposed risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the fractured G2 Filter strut to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

COUNT XIII - FRAUDLENT CONCEALMENT

144. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-143 as though fully set forth herein.

145. At all times relevant to this cause, and as detailed *supra*, Defendants fraudulently concealed material information concerning the G2 Filter and the Recovery Cone Removal System from Plaintiff, Plaintiff's health care providers, and the general medical community relating to the safety and efficacy of these devices.

146. Defendants marketed and labeled the G2 Filter as if it could be legally and safely retrieved using the Recovery Cone Removal System. Defendants concealed, however, that they had never obtained clearance to market the Recovery Cone Removal System from the FDA.

147. Defendants marketed the G2 Filter as being safer and less likely to fracture, migrate, or tilt than other devices, including the Simon Nitinol Filter. Yet, Defendants concealed that they were aware of information suggesting that the G2 Filter was substantially more likely to fracture, migrate, tilt, or perforate the vena cava and other internal organs and cause injuries, than were other available IVC Filters.

148. Defendants were also aware that the longer a device was left implanted, tilt, and migration increased the risk of fracture. Yet, Defendants concealed this information from Plaintiff and her health care providers.

149. Defendants were also aware at the time Plaintiff's filter was distributed that electropolishing reduced the risk of fracture and that it was industry standard for NITINOL medical devices. Yet, Defendants concealed this information from Plaintiff and her physicians.

150. Defendants were also aware that numerous deaths and serious injuries had been confirmed to have be caused by failures of G2 filters. Yet, Defendants concealed this information from Plaintiff and her physicians. Instead, Defendants only warned that people with filters had been reported to die and suffer serious injuries but not that any of these events were confirmed to have been caused by Bard's filters.

151. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by Defendants when they had a duty to disclose those facts. They have kept Plaintiff ignorant of vital information essential to the pursuit of their claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing on their causes of action. Defendants' fraudulent concealment did result in such delay

152. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the RECOVERY®, the G2®, and G2® X Filter Systems.

153. Plaintiff and Plaintiff's health care providers could not reasonably have discovered the claims made herein until at the earliest the device was discovered to have perforated Plaintiff's vena cava wall and learned of her health care providers' inability to remove the filter.

154. The Defendants are and were under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Plaintiff, but instead they concealed them. Defendants' conduct, as described in this complaint, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

155. As a proximate result of Defendants fraudulent concealment, Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, mental anguish, loss of enjoyment of life, and other losses proximately caused by the device. Plaintiff is also exposed risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the fractured G2® Filter strut to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

COUNT IX - NEGLIGENT MISREPRESENTATION

156. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-155 as though fully set forth herein.

157. At all times relevant to this cause, and as detailed *supra*, Bard negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information concerning the G2® Filter that the Defendant's knew or should have known was false and misleading, the defendant's made these false and misleading statements intending that the statements would be would be relied on by the Plaintiff, her health care providers and the general medical community and the Plaintiff and her physicians justifiably relied on the Defendant's false and misleading statements to include, but not limited to, misrepresentations relating to the following subject areas:

a. The safety of the G2 Filter;

b. The efficacy of the G2 Filter;

c. The rate of failure of the G2 Filter; and

d. The approved uses of the G2 Filter.

158. The false and misleading information distributed by Bard to the public, the medical community and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the G2 Filter. Bard made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and warning document that was included in the package of the G2 Filter that was implanted in Plaintiff.

159. The foregoing representations and omissions by Bard were in fact false. and at the time Plaintiff used the G2 Filter, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

160. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the G2 Filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the G2 Filter.

161. The foregoing representations and omissions by Defendants were in fact false. The G2 Filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the G2 Filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the

injuries Plaintiff suffered. Further, the device has a significantly higher rate of failure and injury than do other comparable devices.

162. Further, contrary to Bard's labeling, there is no FDA cleared or approved device to remove the G2 filter once implanted.

163. Plaintiff, Plaintiff's health care providers and general medical community reasonably relied upon misrepresentations and omissions made by Bard where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the G2 Filter.

164. Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Bard was the direct and proximate cause of Plaintiff's injuries as described herein.

165. As a proximate result of the Bard Defendants negligent misrepresentations, Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, mental anguish, loss of enjoyment of life, and other losses proximately caused by the device. Plaintiff is also exposed risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the fractured G2® Filter strut to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

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COUNT X - FRAUDLENT MISREPRESENTATION AS TO BARD

166. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-165 as though fully set forth herein.

167. At all times relevant to this cause, and as detailed *supra*, Defendants intentionally made false statements of material fact to the Plaintiff, Plaintiff's health care providers, and the general medical community or intentionally omitted or intentionally failed to disclose material information concerning the G2® Filter that the Defendant's knew the statements were in fact false and misleading or made the statements knowing they did not know whether the statements were true or false, the Defendants' made these false and misleading statements intending that the statements would be relied on by the Plaintiff, the Plaintiff's health care providers and the general medical community and the Plaintiff and her health care providers relied upon the Defendant's false and misleading statements. The Defendant's false and misleading statements concerned the following material facts and subjects:

a. The safety of the G2;
b. The efficacy of the G2 Filter;
c. The rates of failure of the G2 Filter; and
d. The approved uses of the G2 Filter and Recovery Cone Removal System.

168. The false and misleading information distributed by Defendants to the public, the medical community and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the RECOVERY®, the G2® and the

G2® X Filters. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and warning document that was included in the package of the G2® X Filter that was implanted in Plaintiff.

169. Defendants further falsely labeled the G2 Filter that it could be safely removed by Recovery Cone Removal System.

170. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the RECOVERY®, the G2® and the G2® X Filters and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the RECOVERY®, the G2® and the G2® X Filters.

171. The foregoing representations and omissions by Defendants were in fact false. The RECOVERY®, the G2® and the G2® X Filters are not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the RECOVERY®, the G2® and the G2® X Filters are hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered. Further, the device has a significantly higher rate of failure and injury than do other comparable devices.

172. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use the G2® X Filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

173. Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts regarding the device had not been concealed and misrepresented by Defendants.

174. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the RECOVERY®, the G2® and the G2® X Filters.

175. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the G2® X Filter, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

176. Plaintiff, Plaintiff's health care providers and general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the RECOVERY®, the G2® and the G2® X Filters.

177. Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Defendants' was the direct and proximate cause of Plaintiff's injuries as described herein.

178. As a proximate result of the Bard Defendants fraudulent misrepresentations, Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, mental anguish, loss of enjoyment of life, and other losses proximately caused by the device. Plaintiff is also exposed risk of requiring additional medical and surgical procedures, including

risk of life threatening complications and ongoing medical care to monitor the fractured G2® Filter strut to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

COUNT XI – LOSS OF CONSORTIUM

179. Plaintiff, Gerald O'Neill re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

180. Gerald O'Neill is and was at all times relevant to this action, the legal husband of Denise O'Neill, and they have at all times relevant to this action, lived together as husband and wife.

181. As a proximate result of the personal injuries suffered by Denise O'Neill, as described in this complaint, Gerald O'Neill has been deprived of the benefits of their marriage including her love, affection, society, and consortium, and other wifely duties and actions. Denise O'Neill provided Gerald O'Neill with all of the benefits of a marriage between husband and wife, prior to her implantation with the defective and unreasonably dangerous G2 Filter and resulting injuries described herein.

182. Gerald O'Neill has also suffered the permanent loss of his wife's regular contribution to the household duties and services, which each provides to the household as husband and wife.

183. Gerald O'Neill has also incurred the costs and expenses related to the medical care, treatement, medications, and hospitalizations to which Denise O'Neill was subjected for the physical injuries she suffered as a proximate result of her use of the G2 Filter. Gerald O'Neill

will continue to incur the future costs and expenses related to the care, treatment, medications, and hospitalization of Denise O'Neill due to her injuries from the G2 Filter.

184. Gerald O'Neill has suffered loss of consortium, as described herein, including the past, present, and future loss of his wife's companionship, services, society, and the ability of Denise O'Neill to provide him with the benefits of marriage, including inter alia, loss of contribution to household income and loss of household services, all of which has resulted in his pain, suffering, and mental and emotional distress and worry.

PUNITIVE DAMAGES AS TO BARD

185. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

186. Plaintiff is entitled to an award of punitive and exemplary damages based upon Bard's intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

187. Bard had knowledge of, and were in possession of evidence demonstrating that, the G2® Filter was defective and unreasonably dangerous and had a substantially higher failure rate than did other similar devices on the market. Yet, Bard failed to:

a. Inform or warn Plaintiff or her health care providers of the dangers;

b. To establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the G2® Filter from the market

188. Bard acted to serve their own interests and having reasons to know and consciously disregarding the substantial risk that their product might kill or significantly harm

patients, or significantly injure the rights of others, and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

189. As a direct, proximate, and legal result of Bard's acts and omissions a described herein, and Plaintiff implantation with Bard's defective product, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

PRAYER FOR DAMAGES

WHEREFORE, Plaintiff, DENISE O'NEILL, prays for relief on the entire complaint, as follows:

1. Judgment to be entered against all Bard Defendants on all causes of action of this Complaint and damages suffered;

2. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of action and damages suffered relevant to this action;

3. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-judgment and post judgment interest, as authorized by law on the judgments entered on Plaintiff's behalf; and,

4. Such other relief and damages the court deems just and proper.

WHEREFORE, Plaintiff DENISE O'NEILL prays for relief as to the Bard Defendant's, as follows:

AS TO THE FIRST CAUSE OF ACTION FOR NEGLIGENCE

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. Pre-judgment and post-judgment interest pursuant to the laws of the State of

Florida;

4. Costs of suit incurred herein;

5. Punitive damages; and

6. Such other and further relief as the court may deem just and proper.

AS TO THE SECOND CAUSE OF ACTION FOR NEGLIGENT FAILURE TO WARN

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. Pre-judgment and post-judgment interest pursuant to the laws of the State of Florida;

4. Costs of suit incurred herein;

5. Punitive damages; and

6. Such other and further relief as the court may deem just and proper.

AS TO THE THIRD CAUSE OF ACTION FOR STRICT LIABILITY FAILURE TO WARN

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. Pre-judgment and post-judgment interest pursuant to the laws of the State of Florida;

4. Costs of suit incurred herein;

5. Punitive damages; and

6. Such other and further relief as the court may deem just and proper.

AS TO THE FOURTH CAUSE OF ACTION FOR STRICT LIABILITY DESIGN DEFECT AGAINST

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. Pre-judgment and post-judgment interest pursuant to the laws of the State of Florida;

4. Costs of suit incurred herein;

5. Punitive damages; and

6. Such other and further relief as the court may deem just and proper.

AS TO THE FIFTH CAUSE OF ACTION FOR STRICT LIABILITY MANUFACTURING DEFECT

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. Pre-judgment and post-judgment interest pursuant to the laws of the State of Florida;

4. Costs of suit incurred herein;

5. Punitive damages; and

6. Such other and further relief as the court may deem just and proper.

AS TO THE SIXTH CAUSE OF ACTION FOR BREACH OF EXPRESS WARRANTY OF MERCHANTABILITY

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. Pre-judgment and post-judgment interest pursuant to the laws of the State of Florida;

4. Costs of suit incurred herein;

5. Punitive damages; and

6. Such other and further relief as the court may deem just and proper.

AS TO THE SEVENTH CAUSE OF ACTION FOR BREACH OF IMPLIED WARRANTYOF MERCHANTABILITY

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. Pre-judgment and post-judgment interest pursuant to the laws of the State of Florida;

4. Costs of suit incurred herein;

5. Punitive damages; and

6. Such other and further relief as the court may deem just and proper.

AS TO THE EIGHTH CAUSE OF ACTION FOR FRAUDULENT CONCEALMENT

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. Pre-judgment and post-judgment interest pursuant to the laws of the State of Florida;

4. Costs of suit incurred herein;

5. Punitive damages; and

6. Such other and further relief as the court may deem just and proper.

AS TO THE NINTH CAUSE OF ACTION FOR NEGLIGENT MISREPRESENTATION

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. Pre-judgment and post-judgment interest pursuant to the laws of the State of Florida;

4. Costs of suit incurred herein;

5. Punitive damages; and

6. Such other and further relief as the court may deem just and proper.

AS TO THE TENTH CAUSE OF ACTION FOR FRAUDULMENT MISREPRESENTATION

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. Pre-judgment and post-judgment interest pursuant to the laws of the State of Florida;

4. Costs of suit incurred herein;

5. Punitive damages; and

6. Such other and further relief as the court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: March 17, 2016

Respectfully Submitted,

Lopez McHugh LLP
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CERTIFICATE OF SERVICE

I hereby certify that, this 17th day of March, 2016, I have electronically filed a copy of the above and foregoing with Clerk of the Court using the ECF system, which sent notification of such filing to counsel of record.

/s/*Matthew R. Lopez*